



Product Service

CERTIFICATE

No. Q1N 17 07 31247 081

Holder of Certificate: **Sirona Dental Systems GmbH**



Fabrikstr. 31
64625 Bensheim
GERMANY

Facility(ies):

Sirona Dental Systems GmbH
Fabrikstr. 31, 64625 Bensheim, GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production and Sales of Imaging Systems for Diagnosis as well as Dental Products for Therapy and Diagnosis; Dental Treatment Units including the following Components:

Electrical and Air Driven Dental Instruments:

- Straight and Contrangles Handpieces,
- Turbines,
- Electrical and Air Driven Motors,
- Water and Air Spray Instruments,
- High Frequency Surgery,
- Scalers,
- UV Light for Hardening of Synthetic Fillings, Cleaning-, Disinfection- and Sterilizers Devices,
- Dental Lasers Devices,
- CAD/CAM-Devices for Restoration,
- Laboratory Devices,
- Dental Alloys / Dental Materials,
- Distribution of Abutments and Abutment Screws

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713103327
Valid from: 2017-10-01
Valid until: 2020-09-30

Date, 2017-09-27

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